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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/911,218

Applicant(s)

QIU ET AL.

Examiner

Jennifer Kolb Michener

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Specification***

1. The disclosure is objected to because of the following informalities: several formulas are missing. On page 12 there is no formula (b) provided, merely a blank space. Similarly, formula II on page 14 is missing, along with formula IV on page 15. Similar problems are present on pages 16 and 21-24. On page 29, there is a formula missing and a square of text blocked from view from what appears to be a sticky note present during photocopying. Pages 32, 48-50, and 64-68 also contain missing formulas.

Appropriate correction is required.

### ***Claim Objections***

1. Claims 1, 7, 8, and 11 are objected to because of the following informalities: the word "partial" in claim 1, step (a) should probably be --partially--. The word "herein" in claims 7, 8, and 11 should probably be --wherein--.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-2, 5-6, and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakagawa et al. (U.S. Pat. 5,409,731).

Nakagawa teaches coating a contact lens by dipping in an amino group-containing polymer, followed by a cross-linking agent (abstract). The amino-group containing polymers acts as the "polyelectrolyte tie layer" and the cross-linking agent acts as the "active agent", as required by Applicant.

4. Claims 1-2, 5-6, and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson (U.S. Pat. 6,050,980).

Wilson teaches coating a contact lens by dipping in a solution of hexamethylene diisocyanate to form a tie coat, followed by a thrombo-resistant layer (col. 7, lines 3-8).

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The tie coat acts as the "polyelectrolyte tie layer" and the thromboresistant coating acts as the "active agent", required by Applicant.

5. Claims 1-3, 5-6, 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Takemura et al. (U.S. Pat. 4,876,126).

Takemura teaches coating a medical instrument, such as a contact lens, by treating with a solution of a compound having a reactive functional group to form an undercoat so that a reactive functional group is present at on the substrate surface, and then treating the substrate with a polymer to covalently bond the reactive functional group with the polymer to thereby form a coat of the polymer on the undercoat. The treatment may be accomplished by brushing, dipping, or spin coating. (abstract; col. 4, lines 13, 35-40; col. 6, lines 13-35; col. 8, lines 27-28; col. 11, line 14).

6. Claims 1-4, 6, 12-13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Vanderlaan et al (U.S. Pat. 6,087,415).

Vanderlaan teaches coating biomedical devices, such as contact lenses, with an anti-microbial and hydrophilic coating using a coupling agent (abstract; col. 1, line 59).

Vanderlaan teaches that suitable substrate surfaces should contain hydroxyl groups, amino groups, or both. Therefore, prior to coating with the coupling agent, if the surface to be coated does not contain the requisite functional groups, such groups are incorporated onto the surface (col. 2, lines 39-41 and 48-58). These groups act as polyionic or polycationic tie layers, or both in that the hydroxyl groups are negatively charged and the amine groups are positively charged. The coupling agent is then

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added, which also may act as a polyelectrolytic tie layer to the subsequently applied hydrophilic polymer, said polymer being polyacrylic acid (col. 2, line19; col. 4, lines 42-43).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takemura et al.

Takemura et al. teach that which is disclosed above, but fail to teach multiple tie coat layers and vapor deposition as a coating means.

In regard to the multiple tie coat layers, it is Examiner's position that it would have been obvious to one of ordinary skill in the art to apply two thin coatings instead of one thicker coating with the expectation of similar results. In general, the transposition of process steps or the splitting of one step into two, where the processes are substantially identical or equivalent in terms of function, manner, and result, was held to not patentably distinguish the processes. *Ex parte Rubin*, 128 USPQ 440 (Bd. Pat. App. 1959

In regard to vapor deposition, Examiner takes Official Notice that vapor deposition is known in the art as a commonly used coating technique often useful interchangeably

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with spraying or dipping in coating medical devices with functional groups and active agents. Examiner cites Shah to teach such interchangeability. It would have been obvious to one of ordinary skill in the art to use vapor deposition of a coating layer in lieu of spraying or dipping with the expectation of similar, successful results.

9. Claims 7-11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderlaan et al.

Vanderlaan teaches that which is disclosed above, but fails to specifically teach supplying the hydroxyl and amine functional groups in solution. The other monomers and polymers applied to the substrates of Vanderlaan throughout his invention are supplied in the form of solution. It would have been obvious to one of ordinary skill to coat these functional groups in solution as is taught for the other coating steps of his invention with the expectation of successful results.

In regard to claims 7 and portions of claim 10, when hydroxyl groups are selected as the functional group incorporated onto the substrate prior to the coupling agent, the charges of said group are the opposite of the coupling agent, which contains amino groups.

In regard to claims 9 and selections of claims 10 and 11, Vanderlaan teaches that which is disclosed above, but fails to teach coating by spraying or vapor deposition.

Examiner takes Official Notice that vapor deposition and spraying are well-known coating methods often used interchangeably with dipping for coating medical devices with functional groups and active agents. Examiner cites Shah to teach such

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interchangeability. It would have been obvious to one of ordinary skill in the art to use vapor deposition or spraying a coating layer in lieu of dipping with the expectation of similar, successful results.

As an alternative rejection of claims 7 and 10 and as a new rejection of claims 8 and 11, Examiner notes Vanderlaan's teaching of the option of pre-treating the substrate with amine groups, hydroxyl groups, or both. In the instance when both the amine groups and hydroxyl groups are desired, Vanderlaan teaches oppositely charged polyionic tie layers. Vanderlaan does not provide a specific sequence of coating with both groups, however it is Examiner's position that in a method of coating a substrate with two types of materials, it is inherent that the materials must be either supplied together or separately. In which case, it would have been obvious to one of ordinary skill in the art to supply the two materials either together in one solution or in subsequent steps, separately, with the expectation of similar, successful results.

10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderlaan et al. in view of Takemura.

Vanderlaan teaches that which is disclosed above including dip-coating functionalized materials onto contact lens surfaces. Takemura teaches that which is disclosed above including the interchangeability of dip-coating with spin-coating in applying functionalized materials to contact lens surfaces. Since Vanderlaan teaches dip-coating such materials onto contact lenses and Takemura teaches dip-coating or spin-coating



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materials onto contact lenses, Takemura would have reasonably suggested spin coating in the method of Vanderlaan. It would have been obvious to one of ordinary skill in the art to use Takemura's teaching of the equivalence of dip- and spin-coating in the method of Vanderlaan to provide Vanderlaan with another suitable method of coating contact lenses, with the expectation of successful results.

### ***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener  
March 24, 2002



SHRIVE P. BECK  
SUPERVISORY PATENT EXAMINER  
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